OCT 3 1 2003

# 510(k) Summary

Submitted in accordance with the requirements of 21 CFR 807.92.

Assigned 510(k) number:

## Submitter

Name: CardioComm Solutions Inc.
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Contact: Janet Wainman
Date: September 25th, 2003

## Device

Name: GlobalCardio

Substantial Equivalence is claimed to: GlobalCardio (K013354)

## Description

GlobalCardio is a cardiology software product, delivered over the web using the Application Service Provider (ASP) model. GlobalCardio operates on IBM compatible PCs and runs within an Internet browser, Microsoft Internet Explorer. GlobalCardio operates as a client server application. GlobalCardio presents an interface for health care professionals to input, store, query and output data from a centrally hosted, or client based relational database.

The product is a web-based database system for the secure storage of all aspects of a patient's cardiology record including: arrhythmia follow-up and diagnosis, trans-telephonic pacemaker follow-up, implantable cardioverter defibrillator (ICD) follow-up, in-clinic follow-up, cardiac rehabilitation data, stress test data pathological diagnosis, ECGs, ECG information, clinical history, physician notes, clinical history and associated reports and queries.

GlobalCardio is a comprehensive ECG management system. GlobalCardio is sold in two ways:

- Per-use or fee-for-service. Software is not shipped and installed, but instead customer accounts are set up for access and record management from the centrally hosted web application. Login IDs and passwords are created for

each authorized client. Databases reside in the secure, firewall protected, warehouse at the application host site.

- Technology licensing. GlobalCardio technology is licensed to another company which then hosts a complete service, as described above, including secure data warehousing.

All activity on GlobalCardio is recorded by User ID. User IDs are provided for each customer to access their own secure database(s).

GlobalCardio is designed as a multi-user system capable of supporting large volumes of simultaneous users.

Data can be entered via keyboard, mouse, bar code reader, sound card, serial port, or IrDA port, and stored to and retrieved from any computer media. Information can be displayed on the computer monitor or printed.

GlobalCardio is not a life-supporting or life-sustaining system. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgment and experience are used to check and interpret the data.

## Intended Use

GlobalCardio is intended to be used as a data management tool for cardiologists, general practitioners, cardiac or ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions or care givers to store, retrieve, communicate and report ECG and ECG data acquired from a variety of ECG sources including single and multi-lead ECG devices. GlobalCardio will be accessed over the Internet and data will be stored at either the client site or at the central GlobalCardio data warehouse. Data will be secure, and with separate data stores for each client. Users will be able to access specific modules for managing patient cardiac related data such as arrhythmia data that fit their patients' needs. GlobalCardio is intended for use in clinics, hospitals, physician's offices, or anywhere a medical doctor deems appropriate. GlobalCardio does not offer diagnosis or medical alarms. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgment and experience are used to check and interpret the data.

## Technological Characteristics

Two features in this modified version of GlobalCardio cannot be found in the predicate device (unmodified version of GlobalCardio): the in-clinic pacing follow-up module and the ICD follow-up module. These features allow physicians to store data and generate additional reports based on that data specific to these encounter types, similar to the existing Arrhythmia and Trans-Telephonic Monitoring follow-up modules, which are already supported by the approved (unmodified) device. Thus the modification represents a minor change to the functionality of the product and does not change the indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2003

CardioComm Solutions, Inc.
c/o Ms. Janet Wainman
Quality System Manager
201-3060 Cedar Hill Road
Victoria, British Columbia
Canada V8T 3J5

Re: K033037
Trade Name: GlobalCardio
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: DSH
Dated: September 25, 2003
Received: September 29, 2003

Dear Ms. Wainman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for use

510(k) Number: K~~013354~~

Device Proprietary Name: GlobalCardio

Indications for use:

GlobalCardio is intended to be used as a data management tool for cardiologists, general practitioners, cardiac or ECG technicians, nurses, monitoring service technicians, and other cardiac related institutions or care givers to store, retrieve, communicate and report ECG and ECG data acquired from a variety of ECG sources including single and multi-lead ECG devices. GlobalCardio will be accessed over the Internet and data will be stored at either the client site or at the central GlobalCardio data warehouse. Data will be secure, and with separate data stores for each client. Users will be able to access specific modules for managing patient cardiac related data such as arrhythmia and implantable pulse generator (such as pacemakers, and implantable cardioverter defibrillators) data that fit their patients' needs. GlobalCardio is intended for use in clinics, hospitals, physician's offices, or anywhere a medical doctor deems appropriate. GlobalCardio does not offer diagnosis or medical alarms. It is intended that competent human intervention be involved before any impact on health occurs. Clinical judgment and experience are used to check and interpret the data.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K~~013~~K033037